

PATENT COOPERATION TREATY

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REC'D 15 AUG 2005



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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference CD010PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/IB2004/050314	International filing date (day/month/year) 23.03.2004	Priority date (day/month/year) 25.03.2003
International Patent Classification (IPC) or national classification and IPC A61B17/02, H01L21/331		
Applicant CARDIO INCORPORATED et al.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 5 sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (Indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand 21.10.2004	Date of completion of this report 11.08.2005	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Hamann, J. Telephone No. +49 89 2399-7046 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/IB2004/050314

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-17 as originally filed

Claims, Numbers

1-3, 5-11 received on 02.12.2004 with letter of 16.09.2004

Drawings, Sheets

1/8-8/8 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☒ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☒ the claims, Nos. 4
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-3,6-11
	No: Claims	5
Inventive step (IS)	Yes: Claims	
	No: Claims	1-3,5-11
Industrial applicability (IA)	Yes: Claims	1-3,5-11
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item I

Basis of the report

The applicant has not provided a basis for the amendments of claims 1, 5, and 6 under Article 19(1) PCT.

No basis could be found (Article 19(2) PCT) for the amendments of claim 1 in line 16 ("... and the **curved** portion being provided in the other end of the second grasping plate ...") and in line 22 ("... between the first **grasping** portion of the first grasping plate ..."). It appears, however, that these amendments are acceptable if "**curved** portion" is replaced by "**fixing** portion" (see [88]), and "first **grasping** portion" is replaced by "first **retaining** portion" (see [75]). For the comments under Item V it is presumed that these replacements have been made.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: US-A-5 496 341 (SAUER JUDE S ET AL) 5 March 1996 (1996-03-05)

D2: US-A-4 286 598 (KAPITANOV NIKOLAI N ET AL) 1 September 1981 (1981-09-01)

2.1 The document **D2** discloses a surgical holder with:

grasping member: jaws 4, 5

manipulation member: levers 1, 2

connection portion with fixing tool: e.g. automatic lock 7

first grasping plate: jaw 4

second grasping plate: jaw 5

first grasping portion: e.g. right end of jaws 4, 5 in Fig. 11

second grasping portion: e.g. left end of jaws 4, 5 in Fig. 11

Jaw 4 together with removable part 8 has a U-shape. Therefore, one of its ends, e.g. its right end, is a retaining portion having an opening which is opened toward an outer side of the first grasping plate, and its other end, e.g. its left end, is a supporting portion having a recessed portion.

Analogously, jaw 5 includes a covering portion and a fixing portion.

2.2 Consequently, the present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claim 5** is **not new** in the sense of Article 33(2) PCT.

3 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of **claims 1-3 and 6-11** does **not involve an inventive step** in the sense of Article 33(3) PCT:

3.1 The subject-matter of these claims differs from **D2** (see above) in that the second grasping plate has a "**non-covering portion** which does not cover the first grasping plate", and in that the fixing portion has a "**curved portion**". Both features do not bring about any relevant technical effect connected therewith.

3.2 Dependent **claims 2 and 3**: known measures for the skilled person

4 It should be noted that the subject-matter of **claim 5** does also **not involve an inventive step** in the sense of Article 33(3) PCT over document **D1**:

The document D1 (see Figs. 1-3) discloses a surgical holder with:

grasping member: head 22, head section 47

manipulation member: finger grips 44, 45

connection portion: pivot pin 60

first grasping plate: head 22

second grasping plate: head section 47

first grasping portion: distal ends of head 22 and head section 47

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opening: distal ends of grooves 28

second grasping portion: proximal ends of head 22 and head section 47

The subject-matter of claim 5 differs therefrom only by the provision of a fixing tool, which is so vaguely defined that there is no unitary technical effect connected therewith. Therefore, it is considered a design option.

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Claims

- [1] (Amended) A surgical holder comprising a grasping member for grasping a tissue, a manipulation member for manipulating the grasping member, and a connection portion with one end connected to the manipulation member, wherein: the grasping member includes a first grasping plate, and a second grasping plate provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other; the first grasping plate includes a retaining portion having an opening which is opened toward an outer side of the first grasping plate and a supporting portion having a recessed portion, the opening being provided in one end of the first grasping plate and the recessed portion being provided in the other end of the first grasping plate,
- the second grasping plate includes a covering portion formed so as to cover an entire surface or a part of the opening of the first grasping plate, a non-covering portion which does not cover the first grasping plate, and a fixing portion having a curved portion, the covering portion being provided in one end of the second grasping plate and the curved portion being provided in the other end of the second grasping plate,
- the curved portion opposing the recessed portion to form the tissue grasping space when the first grasping plate and the second grasping plate are positioned so as to oppose on another,
- a first grasping portion which can grasp a part of a tissue between the first grasping portion of the first grasping plate and the covering portion of the second grasping plate are provided in one end portion of the grasping member, and the opening exposing another part of the tissue when a part of a tissue is grasped by the first grasping portion; and
- a second grasping portion which can form a tissue grasping space between the recessed portion of the first grasping plate and the curved portion of the second grasping plate is provided in another end portion of the grasping member.
- [2] A surgical holder according to claim 1, wherein a tissue protection material is attached to an opposing surface of the first grasping plate and/or the second grasping plate.
- [3] A surgical holder according to claim 2, wherein the tissue protection material is permeated with medicines.

AMENDED SHEET (ARTICLE 13)

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- [4] (Canceled)
- [5] (Amended) A surgical holder comprising a grasping member for grasping a tissue, a manipulation member for manipulating the grasping member, and a connection portion with one end connected to the manipulation member and the other end provided with a fixing tool, wherein:

AMENDED SHEET (ARTICLE 19)

AMENDED SHEET

the grasping member includes a first grasping plate, and a second grasping plate provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other;

the grasping member is formed into a rectangular shape with the manipulation member elongated from a side thereof;

a first grasping portion which can grasp a part of a tissue between the first grasping plate and the second grasping plate, and an opening which is provided in the vicinity of the first grasping portion and exposes another part of the tissue are provided in one end portion of the grasping member, the opening being opened at an outer side of the first grasping portion;

a second grasping portion which can form a tissue grasping space between the first grasping plate and the second grasping plate is provided in another end portion of the grasping member, the tissue grasping space and the opening being positioned at respective ends on one axis of the grasping member.

[6]

(Amended) A surgical holder comprising a grasping member for grasping a tissue, a manipulation member for manipulating the grasping member, and a connection portion connected to the manipulation member, wherein:
the grasping member includes a first grasping plate and a second grasping plate provided so as to oppose the first grasping plate in a movable manner so that they are able to become closer to each other or more distanced from each other;
the first grasping plate includes a retaining portion having an opening of a U-shape or substantially a U-shape, and a supporting portion having a recessed portion, the opening being provided in one end of the first grasping plate and the recessed portion being provided in the other end of the first grasping plate;
and

the second grasping plate includes a covering portion formed to cover an entire surface or a part of the opening of the first grasping plate, a non-covering portion which does not cover the first grasping plate, and a fixing portion having a curved portion, the curved portion opposing the recessed portion to form the tissue grasping space when the first grasping plate and the second grasping plate are positioned so as to oppose one another.

[7]

A surgical holder according to claim 6, wherein the tissue to be grasped is a tubular tissue with a surrounding tissue, and the surrounding tissue is grasped by a part which defines the shape of the opening of the first grasping plate and the covering portion of the second grasping plate.

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- [8] A surgical holder according to claim 6, wherein the tissue to be grasped is a tubular tissue, and the tubular tissue is grasped by a tissue grasping space formed by the recessed portion of the first grasping plate and the curved portion of the second grasping plate.
- [9] A surgical holder according to claim 6, wherein the tissue to be grasped is a tubular tissue, and the tubular tissue is grasped with one point of the tubular tissue being grasped by the retaining portion of the first grasping plate and the covering portion of the second grasping plate, and another point being grasped by a tissue grasping space formed by the recessed portion of the first grasping plate and the curved portion of the second grasping plate.
- [10] A surgical holder according to claim 6, wherein the tissue to be grasped is a

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tubular tissue, and an end portion of the retaining portion which defines the opening of the first grasping plate is inserted into a tube of the tubular tissue to grasp the tubular tissue.

[11]

A surgical holder according to claim 6, wherein the tissue to be grasped is a tubular tissue (A), and, (i) with one point of the tubular tissue (A) grasped by the retaining portion of the first grasping plate and the covering portion of the second grasping plate and another point of the tubular tissue (A) grasped by the tissue grasping space formed by the recessed portion of the first grasping plate and the curved portion of the second grasping plate, anastomosis manipulation between a cut portion of the tubular tissue (A) and a cut portion of a tubular tissue (B) positioned on the supporting portion is performed, and then, (ii) with the tubular tissue (A) grasped by the tissue grasping space formed by the recessed portion of the first grasping plate and the curved portion of the second grasping plate, anastomosis manipulation between a cut portion of the tubular tissue (A) and a cut portion of the tubular tissue (C) positioned on the supporting portion is performed.

AMENDED SHEET (ARTICLE 19)